

REMARKS

This Amendment is submitted in response to the Office Action mailed on February 20, 2004. The Office Action rejects Claims 30, 32, and 37-41 under 35 U.S.C. § 112 and Claims 30, 32, and 37-41 under 35 U.S.C. § 103. In response, Claims 30, 35, 37, and 38 have been amended. Applicants respectfully submit that in view of the amendments and/or for the reasons set forth below, the rejections have either been overcome or are improper.

The claims stand rejected under 35 U.S.C. § 112 as not being enabling due to the use of the term "recovery." Further, Claims 37-38 are stated to be dependent on a cancelled claim. Applicants have amended Claims 37 and 38 so that they depend from Claim 30 and therefore the dependency rejection under 35 U.S.C. § 112 has been overcome.

Additionally, Applicants respectfully submit that the enablement rejection is based on an incorrect interpretation of the claims and invention. In this regard, the Patent Office appears to have misunderstood the disclosed experiments. The primary difference between the Feeds 1 - 5 in the specification is not the amino acid content of the protein source as the Patent Office suggests (page 3, lines 13-17 of the Office Action), but the degree of hydrolysis. It is true that there are very small differences between the amino acid contents of Feeds 1 to 5 but these are due to experimental error in the hydrolysis process. It is also true that there are similarly small variations in lipids and minerals between the feeds, again due to experimental error. If the Patent Office believes that the Applicants are trying to rely on the differences in amino acid content as demonstrating an effect, then the Patent Office may be correct about statistics and the view that the effects might be equally well due to differences in the lipid profile. However, the parameter that varies significantly among the feeds is degree of hydrolysis as follows:

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| Feed 1 | intact proteins (degree of hydrolysis, DH, 4.41%, non-protein nitrogen concentration, NPN, 1.1% on the basis of total N) |
| Feed 2 | DH 14%, NPN 54.5% |
| Feed 3 | DH 17.3%, NPN 65.9% |
| Feed 4 | DH 35%, NPN 92.6% |
| Feed 5 | Free amino acids |

It follows that Feed 1 (intact protein is the control). The feeds are within the limits of experimental error and demonstrate enablement.

With respect to the rejection in view of the use of the term “recovery,” Applicants have amended Claim 30, and therefore all of the claims that depend therefrom, to eliminate the statement “a method for promoting recovery of.” The claim now reads “A method for increasing the protein concentration and/or rate of protein synthesis.” The specification provides support for this amendment and therefore this amendment does not add new matter. Moreover, Applicants respectfully submit that the 35 U.S.C. § 112 rejection, which Applicants maintain was not proper, is now moot.

The claims stand rejected under 35 U.S.C. § 103 as being obvious in view of a number of references. Applicants submit that the art fails to disclose or even arguably suggest the claimed invention. Generally speaking, prior to Applicants’ claimed invention, Applicants submit that no one recognized the fact that the degree of hydrolysis of a dietary protein affects not only where in the digestive tract it is absorbed but also the locations at which the nutrients are available. Applicants’ invention is not that hydrolyzed protein are absorbed in the duodenum and less hydrolyzed proteins are absorbed lower in the GI tract, but the surprising discovery is the marked use of the nutrients at the location they are absorbed. Thus, Applicants can use the degree of hydrolysis to target protein synthesis in certain organs.

Claims 30 and 37-41 stand rejected as being unpatentable over *Nakamura* or *Masuda*. In this regard, the Patent Office states that these references disclose agents to promote the recovery of certain organs. In view of the amendment to independent Claim 30, and thereby the claims that depend therefrom, these rejections are now moot.

Claims 30, 37, and 38 stand rejected as being unpatentable over *Gordon* or *Tomita*. The Patent Office appears to suggest that inherently these references, that relate to the skin, “correspond to the ‘recovery of an organ’.” Applicants respectfully submit in view of the amendments to the claims, that this rejection is likewise no longer proper.

Claims 30, 37, and 38 stand rejected as being unpatentable over *Gordon* or *Tomita* in view of *Verma*. For the reasons stated above, Applicants submit this rejection is moot. Moreover, Applicants respectfully submit that this rejection is not proper in that in part it is based on a hindsight reconstruction. Both *Gordon* and *Tomita* relate to products for topical application. *Verma* relates to products for surgical implantation. There is absolutely no rhyme or reason why one skilled in the art viewing a topical application reference would be motivated to combine it with a surgical implantation reference. Therefore, Applicants respectfully submit this rejection is not proper.

Claims 30, 37, and 38 stand rejected under 35 U.S.C. § 103 as being unpatentable over *Smith*. *Smith* relates to the identification in milk of growth factors similar to IGF-1. It should be noted that such growth factors exist in milk independent of its nutritional content. This is in contrast to the present invention wherein the specific dietary milk protein hydrolysate is selected. Thus, Applicants' method of selecting a form of dietary milk protein hydrolysate, specifically required by independent Claim 30, is neither disclosed nor suggested. Therefore, Applicants respectfully submit that *Smith* does not disclose nor suggest the claimed invention.

Claims 30, 32, and 37-41 stand rejected as being unpatentable over *Jolles* as being obvious in view thereof. Again, *Jolles* discloses the administration of a single tripeptide obtained by hydrolysis of human casing as an immunostimulant. Such a product would have a negligible nutritional content. By contrast, the present invention provides sufficient nutritional value of the protein and merely varies the targeted organ. Thus, in the examples set forth by the Patent Office, the proposed hypothetical rat would die of malnutrition. Accordingly, Applicants respectfully submit that the rejection is not proper, in part, in that the reasons provided by the Patent Office for justifying the rejection demonstrates the rejection is not proper. Further, the reference does not disclose or suggest Claim 30 as now amended.

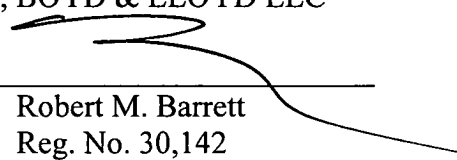
Lastly, Claims 30, 32, and 37-40 stand rejected as being unpatentable over *Vickery*. *Vickery* is not prior art to the present application. *Vickery* has a priority date of May 28, 1998. Applicants' present application has a priority date of September 16, 1997. Therefore, Applicants respectfully request that this rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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